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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,279	05/15/2001	Theo Kirkland	TSRI 372.0 D2	3986

26621 7590 08/26/2003

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/26/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/858,279

Applicant(s)

KIRKLAND ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,6-8,12,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,6-8,12, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendments filed June 17, 2003 has been entered. Claims 1-2, 4-5, 9-11 and 13 have been cancelled. Claims 3, 6-8 and 12 have been amended. Claims 3, 6-8, 12 and 21-22 are under consideration in this office action.

Drawings

2. The drawings filed on June 17, 2003 are acceptable.

Withdrawal of Rejections

3. The following rejections have been withdrawn in view of applicants' amendments and arguments:

- a) the scope of enablement rejection of claims 5-8 and 21-22 under 35 U.S.C. 112, first paragraph;
- b) the deposit rejection of claims 1-13 and 21- under 35 U.S.C. 112, first paragraph;
- c) the judicially created doctrine of obviousness-type double patenting rejection of claims 1-13 and 21-22; and
- d) the rejection of claims 1-8 and 11-13 under 35 U.S.C. 102(b) as being anticipated by Pugin et al.

Response to Arguments

4. Applicant's arguments filed June 17, 2003 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

5. The judicially created doctrine of obviousness-type double patenting rejection of claims 3, 6-8, and 21-22 is maintained over claims 1-5 and 8-15 of U.S. Patent No. 5,753,504.

Applicants assert that because the claims of U.S. Patent No. 5,753,504 do not recite the additional limitation that the monoclonal antibody including a binding specificity to LBP, to denatured LBP, and to a complex containing LBP and LPS of Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4 or Mab 24B7, the double patenting rejection should be withdrawn.

However it is the examiner's position that even though the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a monoclonal antibody that immunoreacts with lipopolysaccharide binding protein (LBP) but does not substantially inhibit LBP binding the LPS; the monoclonal antibody inhibits LBP-mediated binding of LPS to CD14; inhibits LBP-mediated LPS dependant activation of myeloid cells; inhibits LBP-mediated LPS dependant secretion of tumor necrosis factor from myeloid cells; a hybridoma cell line that produces the monoclonal antibody; and a pharmaceutical composition comprising the antibody, just as recited by the instant claims.

The statement the monoclonal antibody including a binding specificity to LBP, to denatured LBP, and to a complex containing LBP and LPS of Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4 or Mab 24B7 does not create a different structural antibody when compared to the antibodies claimed in patent 5,753,504. Moreover the antibodies

of the patent 5,753,504 inherently encompass the same characteristics, i.e., the ability to bind specifically to LBP, to denatured LBP, and to a complex containing LBP and LPS of Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4 or Mab 24B7.

Claimed monoclonal antibodies 1E8 and 2B5 of patent 5,753,504 were shown to demonstrate inhibition of binding of LPS by CD14-expressing CHO cells. Mab 2B5 was shown to block the release of TNF. Therefore the monoclonal antibodies of patent 5,753,504 inherently meet the limitations described by the instant claims. The instant claims recite language that encompasses the antibodies of patent 5,753,504. Therefore, the monoclonal antibodies, hybridoma cell lines and pharmaceutical compositions are not patentably distinct and the rejection is maintained.

Claim Rejections - 35 USC § 102

6. The rejection of claims 3, 6-8, 12 and 21-22 under 35 U.S.C. 102(b) as being anticipated by Leturcq et al., is maintained for reasons already of record. The rejection was on the grounds that Leturcq et al., teach the generation of monoclonal antibodies that immunoreact with lipopolysaccharide binding protein (LBP) but do not substantially inhibit LBP binding the LPS. The monoclonal antibodies can bind to LBP even when it is complexed to LPS and recognized denatured LBP. Some of the monoclonal antibodies taught include Mab 8C9 and Mab 18G4.

Applicants assert that because the amended claims recite the additional limitation that the monoclonal antibody including a binding specificity to LBP, to

Art Unit: 1645

denatured LBP, and to a complex containing LBP and LPS of Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4 or Mab 24B7, the rejection should be withdrawn.

In response to applicant's argument, a recitation of the intended function of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the function, then it meets the claim. The prior art antibodies immunoreacts with lipopolysaccharide binding protein (LBP) but does not substantially inhibit LBP binding the LPS. The prior art discloses that generation of the monoclonal antibodies via hybridomas, and as applicants stated that hybridoma techniques and screening assays, are well within the knowledge of the art and one skilled in the art could produce monoclonal antibodies and corresponding hybridoma cell lines with routine experimentation.

Monoclonal antibodies 1E8, 2B5 and 18G4 taught by Leturcq et al., are the same antibodies which the instant application teaches as being able to inhibit the binding of LPS by CD14-expressing CHO cells, and shown to block the release of TNF from myeloid cells. Therefor Leturcq et al., teach monoclonal antibodies with the same structure and functional abilities as those recited by the instant claims. The additional limitation that the monoclonal antibody including a binding specificity to LBP, to denatured LBP, and to a complex containing LBP and LPS of Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4 or Mab 24B7 does not change the structure of the claimed antibody, rather it describes binding specificities which the prior art antibodies are capable of meeting. Since the Patent Office does not have the facilities for examining

and comparing applicants' peptide with the peptide of the prior art reference, the burden is upon the applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed monoclonal antibody of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Therefore in view of the reasons above, the rejection over Leturcq et al., is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3,6 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3, 6, and 12 are drawn to a monoclonal antibody or hybridoma cell line producing the monoclonal antibody wherein "the monoclonal antibody including a binding specificity to LBP, to denatured LBP, and to a complex containing LBP and LPS of Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4 or Mab 24B7."

However it is unclear the antibody includes binding specificities to LBP, to denatured LBP, and to a complex containing LBP and LPS of Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4 or Mab 24B7. It is unclear if the statement is

implying that the claimed antibody will specifically bind to LBP, to denatured LBP, and to a complex containing LBP and LPS of Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4 or Mab 24B7. Furthermore the recitation that the antibody includes binding specificities to a complex containing LBP and LPS of Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4 or Mab 24B7 is unclear. What is a complex of LBP and LPS of Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4 or Mab 24B7?

Therefore it is unclear how to define the monoclonal antibody including a binding specificity to LBP, to denatured LBP, and to a complex containing LBP and LPS of Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4 or Mab 24B7 as recited by the claims. Clarification is therefore requested to overcome this rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


Art Unit: 1645


the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines 
August 21, 2003


LYNETTE R. F. SMITH
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